

## Message Text

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61

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 ISO-00 OES-06 MED-03 /038 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: PFF

APPROVED BY OES/APT/B;P: WJWALSH, III

DHEW/OIH: MACODDING

EUR/NE:KHSHIRLEY(INFO)

ARA/MEX:GFALK(INFO)

ARA/NC:DWCOX(INFO)

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P 141946Z JUL 76

FM SECSTATE WASHDC

TO AMEMBASSY BOGOTA PRIORITY

AMEMBASSY MEXICO

AMEMBASSY THE HAGUE

UNCLAS STATE 174244

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, CO, MX, NL

SUBJECT: FDA ADVISORY - RECALL NO. T-111-6 AND

T-112-6

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED:

A. RECALL T-111-6: STANICOR-KAPPA IMPLANTABLE R-WAVE  
INHIBITED CARDIAC PACER, MODEL 171, IN STAINLESS STEEL  
HERMETICALLY SEALED CASE.

B. RECALL T-112-6: ECTOCOR-KAPPA IMPLANTABLE R-WAVE  
SYNCHRONOUS CARDIAC PACER, MODEL 172, IN STAINLESS STEEL  
HERMETICALLY SEALED CASE.

2. INDIVIDUAL PACER SERIAL NUMBERS ARE INVOLVED RATHER  
THAN LOT NUMBERS. ALL SERIAL NUMBERS OF MODEL 171

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STANICOR-KAPPA PACER AND MODEL 172 ECTOCOR-KAPPA PACER

WHICH HAVE NOT BEEN IMPLANTED ARE UNDER RECALL. THOSE UNITS (SERIAL NUMBERS) WHICH HAVE BEEN IMPLANTED ARE SUBJECT TO INTENSIFIED MONITORING BY THE PATIENTS PHYSICIAN.

3. MANUFACTURER/RECALLING FIRM:

CORDIS CORPORATION  
3901 BISCAYNE BOULEVARD  
MIAMI, FLORIDA 33137

4. REASON FOR ADVISORY - RECALL:

DEFECTIVE WELDING HAS BEEN DOCUMENTED IN THE HERMETICALLY SEALED, STAINLESS STEEL CASING OF THE STANICOR-KAPPA PACERS MODEL NO. 171. A SIMILAR CASING IS USED FOR THE ECTOCOR-KAPPA PACERS OF MODEL NO. 172. THERE HAVE BEEN NO DOCUMENTED FAILURES OF THE ECTOCOR-KAPPA PACERS TO DATE, HOWEVER, DUE TO SIMILAR CASING OF THE ECTOCOR-KAPPA MODEL, IT IS INCLUDED IN THIS RECALL.

THE DEFECTIVE WELDING CAN LEAD TO CORROSION IN THE WELD (PITTING). CORROSION OF THE WELD WOULD ALLOW THE ENTRY OF MOISTURE FROM BODY FLUIDS INTO THE INTERNAL AREA OF THE PACER. THIS MOISTURE COULD CAUSE A MALFUNCTION OF THE ELECTRONIC CIRCUITRY AND INFECTION OR IRRITATION OF THE PATIENT'S TISSUE. THE POSSIBLE PREMATURE FAILURE OF THE ELECTRONIC CIRCUITRY POSES A HEALTH HAZARD OF A POTENTIALLY LIFE THREATENING NATURE TO PACER DEPENDENT PATIENTS.

ON 5/3/76, CORDIS REPRESENTATIVES INFORMED THE BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS OF THE DEFECTIVE WELDS FOR THE STANICOR-KAPPA PACER. A SHIPPING FREEZE ON ALL KAPPA PACERS HAD BEEN IN EFFECT SINCE 4/30/76. FDA'S GENERAL COUNSEL REQUESTED THAT A DETAILED LETTER LISTING KNOWN FAILURES AND SIDE EFFECTS OF THE KAPPA PACERS BE SENT TO 30 PHYSICIANS WHO HAD IMPLANTED THE EARLIEST KAPPA PACERS (BETWEEN OCTOBER 1974 THROUGH MARCH 1975).  
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THIS LETTER DATED AND MAILED ON 5/7/76, TOLD THESE PHYSICIANS OF ALL KNOWN FAILURE MODES OF THE KAPPA PACERS INCLUDING LIMITED INFORMATION ON ONE CLINICAL FAILURE DUE TO CORROSION OF THE WELD OF THE CASE. BY LETTER DATED 5/26/76, CORDIS RECALL NOTICES WERE SENT TO ALL IMPLANTING AND MONITORING PHYSICIANS, OF RECORD FOR KAPPA PACERS. IN THE RECALL LETTER, CORDIS REQUESTED THAT ALL NON-IMPLANTED PACERS BE RETURNED TO THE FIRM.

THEY ALSO REQUESTED THAT PATIENTS WITH KAPPA PACERS IMPLANTED BE MONITORED AT LEAST MONTHLY AFTER THE FIRST 10 MONTHS POST-IMPLANT. THE LETTER FURTHER STATES THAT THE PHYSICIANS CONSIDER ELECTIVE REPLACEMENT OF THE PACER AT 10 MONTHS FOR PACER DEPENDENT PATIENTS.

THE 10 MONTH PERIOD WAS CHOSEN AS A GUIDE BASED UPON TWO FIELD FAILURES DOCUMENTED AT 12 AND 15 MONTHS. A TWO MONTH SAFETY MARGIN WAS SUBTRACTED FROM THE SHORTER POST-IMPLANT FAILURE AND WAS CHOSEN AS A BASE.

ON 5/26/76, CORDIS ALSO MAILED DEAR DOCTOR LETTERS TO THE MEDICAL DIRECTORS OF ALL CONSIGNMENT HOSPITALS. NON-IMPLANTED PACERS ARE TO BE RETURNED TO CORDIS. IMPLANTED PACERS THAT HAD NOT YET BEEN REGISTERED WITH CORDIS WERE TO BE IDENTIFIED AND PATIENT INFORMATION WAS TO BE SENT TO CORDIS. DISTRIBUTION OF KAPPA PACERS INVOLVED IN THIS RECALL NOTIFICATION COMMENCED IN THE FALL OF 1974 AND WAS DISCONTINUED ON 4/30/76. THERE WAS NO DISTRIBUTION OF KAPPA PACERS FROM APRIL 1975 THROUGH JULY 1975 NOR FROM NOVEMBER 1975 THROUGH FEBRUARY 1976. THE TOTAL NUMBER OF PACERS POSSIBLY IN ACTIVE CHANNELS IS ESTIMATED TO BE 1,897.

5. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED THE RECALL NOTIFICATIONS DATED 5/26/76. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED TO THE CORDIS CORPORATION.

6. FOREIGN CONSIGNEES AS FOLLOWS:

A. CORDIS-EUROPA  
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RODEN  
THE NETHERLANDS

B. MAX MEYER INDENT  
OFICINA-702  
CARRERA 5A 16-14  
BOGOTA  
COLOMBIA

C. MEDICINA TECNICA S.A.  
ATTENTION: DR. MIGUEL COSIO PASCAL  
ALVARO OBREGON 242-4 PISO  
MEXICO 7, D.F. KISSINGER

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
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**Copy:** SINGLE  
**Draft Date:** 14 JUL 1976  
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**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
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**TAGS:** OGEN, ETRD, EIND, TBIO, CO, MX, NL  
**To:** BOGOTA THE HAGUE  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006